APR 2 1 2014

SECTION 005
510(k) Summary
[As Required By 21 CFR 807.92(a)]

A. Sponsor
Submitter's Name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767

Primary Contact: Hannah Foley
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B. Date Prepared: February 6, 2014

C. Device Name and Classification:

Proprietary Name: **ENVOY® Guiding Catheter**

Common/Usual Name: Catheter, Percutaneous

Classification Name: Percutaneous Catheter (21 CFR 870.1250), Class II

Product Code: DQY

D. Predicate Devices

This 510(k) submission provides pre-market notification for the proposed ENVOY® Guiding Catheter line extension. The line extension will include a new diameter size 7 French (Fr) with same lengths, pre-shaped configurations and XB (extra backup) options as the predicate ENVOY® 6 French (Fr) Guiding Catheter. The proposed line extension has not altered the fundamental technology or the predicate device's intended use.

Table 1: Prior 510(k) Clearances

510(k) Number	Date Cleared	Name	Manufacturer	Product Code	Predicate For:
Predicate K093184	11/06/2009	ENVOY® Guiding Catheters	Codman & Shurtleff. Inc.	DQY	Intended Use Design Materials Manufacturing Sterilization Packaging

E. Device Description

The ENVOY® Guiding Catheter is a single lumen, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional/diagnostic devices. The guiding catheter is pre-shaped to facilitate positioning.

F. Indications for Use

The ENVOY® Guiding Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

G. Summary of Technological Characteristics of the Proposed Device to the Predicate Device

The proposed 7Fr ENVOY® Guiding Catheter is substantially equivalent to the predicate ENVOY® Guiding Catheter (K093184). No new technological characteristics are being introduced with the proposed device. The proposed ENVOY® Guiding Catheter has the same intended use, function, mechanism of action, clinical utility, design, manufacturing process and sterilization process as the predicate ENVOY® Guiding Catheter. The proposed ENVOY® Guiding Catheter also has the same materials as the current ENVOY® Guiding Catheter (K093184) except for the orange ink used on the ID Band. The proposed ENVOY® 7Fr Guiding Catheter was shown to be substantially equivalent to the predicate device through comparison of indications for use, function, operating principle, bench testing, biocompatibility, and materials. A summary table including characteristics of the proposed device compared with those of the predicate device is provided in **Table 2.**

Table 2: Predicate Comparison Profile

Description	Predicate Device: ENVOY® 6Fr Guiding Catheter (K093184)	This Submission: ENVOY® 7Fr Guiding Catheter
Indications for Use	The Envoy Guiding Catheter is intended for use in the peripheral, coronary and neuro vasculature for the intravascular introduction of interventional/ diagnostic devices	Same predicate
Device Description	The ENVOY® Guiding Catheter is a single lumen, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The guiding catheter is preshaped to facilitate positioning.	Same predicate
Product Code	DQY	Same as predicate
Classification	21 CFR 870.1250, Class II	Same as predicate
Length/ Working Length (cm)	90cm & 100cm	Same as predicate
Catheter Inner Diameter	0.070" (1.8mm)	**0.078" (2.0mm)**
Catheter Outer Diameter	6.0F (0.082"/2.0mm)	**7.0F (0.092"/2.3mm)**
Shapes	Straight Multi-purpose D (MPD) Multi-purpose C (MPC) Modified Cerebral (Burke)(CBL) Head-hunter 1 (HI) Simmons 2	Same as predicate
Reinforcing Member (Braid)	Stainless Steel	Same as predicate
Liner	PTFE Liner	Same as predicate
Sterilization	EtO	Same as predicate
Product Shelf-Life	3year	Same as predicate

H. Summary of Nonclinical Testing

The proposed ENVOY® Guiding Catheter has the same intended use, function, mechanism of action, clinical utility, design, manufacturing process and sterilization process as the predicate ENVOY® Guiding Catheter. The proposed ENVOY® Guiding Catheter also has the same materials as the current ENVOY® Guiding Catheter (K093184) except for the orange ink used on the ID Band. The testing conducted to assess the line extension includes performance assessments per the following recognized standards:

Table 3: Performance Standards

Standard/Guidance/Directive	Description
BS EN ISO 11607- 1: 2009	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials. Sterile Barrier Systems and Packaging Systems
BS EN ISO 11135-1: 2007	Sterilization of Healthcare products Ethylene Oxide: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 10993-7: 2008	Biological Evaluation of medical devices: Ethylene oxide sterilization residuals – Part 7
BS EN ISO 10555-1: 2009	Sterile, single use intravascular catheters Part 1: General requirements; Sterile
ISO 594-1: 1986 (E)	Conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 1 – General Requirements
ISO 594-2 : 1998 (E)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 2 – Local fittings
AAMI / ANSI HE75 : 2009	Human Factors Engineering – Design of Medical Devices
BS EN ISO 10993-1: 2009	Biological evaluation of medical devices: Evaluation & Testing – Part 1
BS EN ISO 10993-5: 2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-4: 2009	Biological evaluation of medical devices Part 4: Selection for tests for interactions with blood
USP <661> (2013)	Containers – Plastic, Physicochemical Tests
ISO 14971: 2012	Medical Devices – Application of risk management to medical device
BS EN ISO 15223-1: 2012	Medical Device – Symbols to be used with medical device labels, labeling and information to be supplied

Bench Testing

Results of verification and validation testing that was conducted on the proposed ENVOY® Guiding Catheter demonstrates that it performs as designed, is suitable for its intended use, is substantially equivalent to the predicate device and therefore, does not raise any new questions of safety and effectiveness. Appropriate testing was identified based on a review of the products' risk analyses and previous validation and verification testing.

The following Verification and Validation tests were conducted to verify the modified design ENVOY® Guiding Catheter:

- Visual Inspection
- Catheter Shape
- Catheter Dimensional Verification
- Tensile Strength Testing
- System Liquid Leakage Testing
- Lateral Stiffness Testing
- Linear Stiffness Testing

- Back-Up Support
- Track Testing
- Sheath Introducer Compatibility
- Multiple In-dwelling device

The following Biocompatibility Testing was conducted with the proposed ENVOY® Guiding Catheter:

- Cytotoxicity: MEM Elution
- Hemocompatibility – In vitro Hemolysis (Direct & Extract)
- USP Physicochemical Aqueous Extraction Test

I. Animal Testing

No animal studies were required as appropriate verification and validation of the ENVOY® Guiding Catheter line extension was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

J. Summary of Clinical testing:

No clinical studies were required as appropriate verification and validation of the ENVOY® Guiding Catheter line extension was achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Conclusion:

Based upon the design, materials, function, intended use, and the non-clinical testing performed by Codman it is concluded that the proposed ENVOY® 7Fr Guiding Catheter is substantially equivalent to the predicate ENVOY® 6Fr Guiding Catheter (K093184), and therefore, does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 21, 2014

Codman & Shurtleff, Inc.
Hannah Foley
325 Paramount Dr.
Raynham, MA 02767-0350 US

Re: K140307
Trade/Device Name: ENVOY Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 21, 2014
Received: March 23, 2014

Dear Hannah Foley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if Known): K140307

Device Name: ENVOY® Guiding Catheter

Indications for Use:

The ENVOY® Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Prescription Use: X **AND/OR** **Over-The-Counter Use:**
(Part 21 CFR 801Subpart D) **(Part 21 CFR 807 Subpart C)**

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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